

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

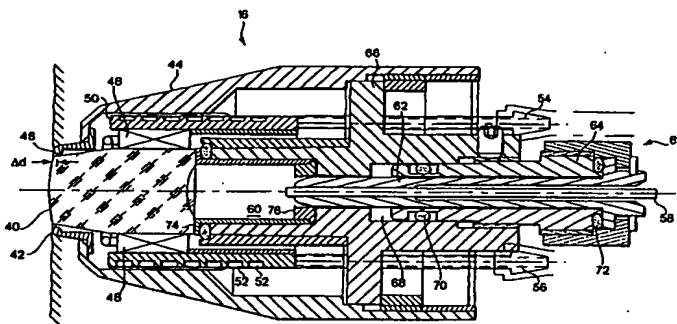
This Page Blank (uspto)



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/06		A1	(11) International Publication Number: WO 99/46005
			(43) International Publication Date: 16 September 1999 (16.09.99)
(21) International Application Number: PCT/US99/05501 (22) International Filing Date: 12 March 1999 (12.03.99) (30) Priority Data: 60/077,794 12 March 1998 (12.03.98) US 09/078,055 13 May 1998 (13.05.98) US 60/115,447 8 January 1999 (08.01.99) US (71) Applicant: PALOMAR MEDICAL TECHNOLOGIES, INC. [US/US]; 45 Hartwell Avenue, Lexington, MA 02173 (US). (72) Inventor: ALTSHULER, Gregory; 45 Hartwell Avenue, Lexington, MA 02173 (US). (74) Agent: KRANS DORF, Ronald, J.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: SYSTEM FOR ELECTROMAGNETIC RADIATION OF THE SKIN



(57) Abstract

A system for treating a selected dermatologic problem and a head for use with such system are provided. The head may include an optical waveguide having a first end to which EM radiation appropriate for treating the condition is applied. The waveguide also has a skin-contacting second end opposite the first end, a temperature sensor being located within a few millimeters, and preferably within 1 to 2 millimeters, of the second end of the waveguide. A temperature sensor may be similarly located in other skin contacting portions of the head. A mechanism is preferably also provided for removing heat from the waveguide and, for preferred embodiments, the second end of the head which is in contact with the skin has a reflection aperture which is substantially as great as the radiation back-scatter aperture from the patient's skin. Such aperture may be the aperture at the second end of the waveguide or a reflection plate or surface of appropriate size may surround the waveguide or other light path at its second end. The portion of the back-scattered radiation entering the waveguide is substantially internally reflected therein, with a reflector being provided, preferably at the first end of the waveguide, for returning back-scattered light to the patient's skin. The reflector may be angle dependent so as to more strongly reflect back-scattered light more perpendicular to the skin surface than back-scattered radiation more parallel to the skin surface. Controls are also provided responsive to the temperature sensing for determining temperature at a predetermined depth in the patient's skin, for example at the DE junction, and for utilizing this information to detect good thermal contact between the head and the patient's skin and to otherwise control treatment. The head may also have a mechanism for forming a reflecting chamber under the waveguide and drawing a fold of skin therein, or for providing a second enlarged waveguide to expand the optical aperture of the radiation.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

SYSTEM FOR ELECTROMAGNETIC RADIATION OF THE SKIN

Related Applications

5 This application is a continuation in part of application Serial No. 08/759,036, and of application Serial No. 08/759,136, both filed December 2, 1996, and of application Serial No. 09/078,055, filed May 13, 1998 and claims priority of provision application No. 60/077,794 and provisional application No. 60/115,447, filed January 8, 1999, which applications are all incorporated herein by reference.

Field of the Invention

10 This invention relates to the utilization of electromagnetic (EM) radiation for treating selected dermatologic problems, and more particularly to a system which utilizes temperature detection at a waveguide through which radiation is being applied to the patient's skin to perform
15 various control functions and to a head usable in such system or elsewhere, which head includes efficient reflectors for back-scattered radiation and/or for otherwise enhancing irradiation of a target volume containing the dermatologic problem.

Background of the Invention

20 Lasers, lamps and other sources of electromagnetic radiation are being increasingly utilized to treat various dermatological conditions, and in particular for the removal of unwanted hair, spider veins, leg veins, other veins or blood vessels which are visible through the patient's skin, lesions, port-wine stains, tattoos and the like. One problem with such treatments is that the only way to get the radiation to a target volume in the dermis where treatment is desired is to
25 transmit the radiation to such volume through the overlying epidermis. Further, since many of the treatments involve absorption of energy by melanin in the dermal volume being treated, for example in a hair follicle, and there is also melanin in the epidermis, particularly in the portion thereof at the dermal/epidermal (DE) junction, the EM radiation used for treatment is generally also absorbed to varying degrees in the epidermis. Further, the deeper in the dermis the treatment
30 is desired and/or the larger the element being treated, the more energy must be used, this generally involving use of a more powerful laser or other radiation source with higher fluence and/or operating such source for longer time durations. However, as the energy applied through

the epidermis increases, the potential for damage to the epidermis as a result of energy absorption therein also increases.

Therefore, one limitation on the energies which can be used for various dermatological treatments in the dermis, and in particular on the depths in the dermis at which treatment can be performed, and on the size of the elements which can be treated, is that the energy applied cannot be so high as to cause appreciable damage to the epidermis. Various ways around this problem have been proposed in the prior art, most of which involve some cooling of the epidermis prior to and/or during treatment to limit or prevent thermal damage thereto. Examples of such procedures include applying cryogenic or other cooling sprays to the skin, applying a cooling gel to the skin, applying radiation through a cold-pack in contact with the skin or through an applicator which is cooled by flowing water, flowing air, or the like. However, these prior art systems have not been wholly satisfactory. One reason for this is that, since most of the absorption is in the melanin located in the lower portions of the epidermis, it is desirable to have cooling through the entire epidermal layer, which is typically about 0.1 mm thick. However, it is not desirable that the cooling extend significantly below the DE junction into the dermal layer since cooling in the dermal layer can potentially inhibit the desired thermal damage to follicles, blood vessels or the like in this region. Further, there are significant variations in radiation absorption by a patients skin, not only among different individuals, people having darker skin absorbing more radiation and being more prone to epidermal damage than people with lighter skin, but even for different areas on the body of a single individual. Therefore, cooling which is not customized to the treatment area generally results in the cooling not being to the proper depth, a problem which can interfere with treatment and/or permit thermal damage to the epidermis.

It would therefore be desirable if the temperature at a selected depth in the skin, for example the DE junction, could be measured, and this temperature utilized to control skin temperature. for example through the epidermis, by some combination of controlling the laser energy applied to skin and/or controlling cooling applied to the skin. However, while infrared sensors have for example been utilized in the past to detect temperature at the surface of the skin, such detection does not provide an accurate indication of temperature even at the skin surface, these readings varying with such factors as skin layer thickness, skin roughness and skin color in addition to temperature. Infrared sensors also provide virtually no information as to skin temperature at a depth below the surface. Therefore, such detection has heretofore been used

only for gross controls, for example to turn off the laser if an emergency temperature threshold is exceeded or the like, but not to fine tune energy application and/or cooling so as to maintain a desired temperature at a selected depth, for example at the DE junction, thereby facilitating a desired treatment without epidermal damage.

5 A need therefore exists for an improved technique which permits more accurate determinations of skin temperature at various depths, including at the DE junction, so as to permit more accurate and more automatic control of EM radiation treatments for various dermatological conditions. In particular, because of variations in skin pigmentation, differences in epidermal depth, and other dermatological differences among patients, laser dermatology procedures are
10 now performed almost exclusively by physicians or other highly trained individuals, and such individuals must exercise great care to assure that epidermal damage does not occur, while still achieving the desired therapeutic effect. More accurate measurement of temperature at desired depths would make treatments by such skilled personnel easier to perform and would permit such procedures to be safely performed by less highly trained, and therefore less expensive, personnel.
15 Such skin temperature measurements could also be utilized to determine skin type/pigmentation for the patient and/or for the part of a patient's body being treated and/or for other purposes.

Where cooling of the epidermis is achieved by placing a cooled applicator or other cooled body in contact with the patient's skin, the contact must be made with sufficient pressure to assure good thermal contact between the cooled body and the skin. However, differences in skin
20 thickness and elasticity, differences in bone backing and other factors affect the pressure required to achieve good thermal contact for different patients and for different areas on the body for the same patient. This is another reason why highly trained and skilled individuals are required for performing the treatments and contributes to the high cost of the treatment. It would therefore be preferable if an automatic technique could be provided for detecting, and thus assuring, good
25 thermal contact between a cooling element and the patient's skin. Such a technique or mechanism, by assuring good thermal contact with the skin before the radiation source is fired, could solve two critical safety problems for radiation dermatology. First, it assures adequate cooling of the epidermis before heating thereof through energy absorption; and second, it assures that the radiation will not be accidentally applied to the eyes or other unwanted place.

30 Related but opposite problems arise in performing certain skin resurfacing/wrinkle removal procedures where the objective is to heat and destroy only the most surface layer of the skin, for example the epidermis, with minimal damage to underlying layers. This requires tight

control of factors such as laser energy, pulse duration and repetition rate. However, variations in patient's skin make such tight control difficult even for highly trained and skilled personnel. Similar problems also arise in other dermatological procedures involving lasers or other radiation sources.

5 Another related problem in using an EM radiation source for dermatological treatment is that the skin reflects back a significant portion of the radiation applied thereto. Since this reflected energy does not reach the treatment site, a higher energy radiation source is required to achieve the desired dermatological treatment than would be the case if a larger percentage of the applied radiation reached the treatment site. It has previously been suggested that one solution
10 to this problem is to provide a retro-reflector which collects and returns such back-scattered radiation to the patient's skin. However, existing retro-reflector devices have not optimized the collection and return of such back-scattered radiation and improved techniques for the more efficient reutilization of back-scattered radiation is therefore desirable. One particular problem with prior art retroreflectors is that they reflect all back-scattered radiation at substantially the
15 same angle the radiation was received; however, radiation at an angle more parallel than perpendicular to the skin surface generally does not reach the treatment area and therefore only heats the surface of the skin, contributing to thermal damage of the skin, without having any beneficial/therapeutic effect. A retroreflection technique which does not contribute to or increase this "parallel" radiation would therefore be desirable.

20 Two other factors can contribute to the efficiency of dermatologic treatments. The first factor is "spot size" or in other words the optical aperture of the applied radiation. Spot size is typically limited by the optics of the handpiece utilized and by the desired fluence as a function of the available energy source. However, a larger spot size permits treatment of large body areas such as back or legs to be accomplished much more quickly, something which enhances both
25 patient satisfaction and practitioner profitability. A technique for facilitating larger spot sizes is thus desirable.

Secondly, anything which reduces the distance from the irradiation source to the target area reduces the amount of energy required to achieve a desired therapeutic effect and anything which permits more of the applied energy to reach the target area has a similar effect. Techniques
30 which facilitate the achievements of these objectives are therefore also desirable.

Summary of the Invention

In accordance with the above, this invention provides both a system for treating a selected dermatologic problem and a head for use in such system. The head, for preferred embodiments includes an optical waveguide or other light path for directing EM radiation of a wavelength appropriate for treating the selected patient dermatologic problem to a first end of the waveguide, the waveguide also having a skin-contacting second end which is opposite the first end; and a sensor at the second end of the waveguide, or otherwise closely adjacent a skin-contacting surface of the head, which senses the temperature thereat. For preferred embodiments, the head also includes a mechanism for removing heat from the waveguide. In order to achieve commercially useful sensitivity, it is preferable that the sensor be located no more than a few millimeters from the skin-contacting surface of the head, for example, the second end of the waveguide, the end contacting the patient's skin. Therefore, for preferred embodiments, the sensor is located within 5 mm of the second end of the waveguide, and for the most preferred embodiments the sensor is located within 1 mm of the second end.

Where a mechanism for removing heat is provided, such mechanism preferably includes a thermoelectric device having one side in thermal contact with the waveguide and an opposite side in thermal contact with a temperature sink. For a preferred embodiment of the invention, back-scattered radiation is substantially internally reflected within the optical waveguide, and there is a reflector within the waveguide for returning back-scattered radiation through the waveguide to the patient's skin. While the reflector may be at a variety of locations within the waveguide, for a preferred embodiment, it is located at the first end of the waveguide. The reflector may also be along sides of the waveguide and the coefficient of reflection for areas of the reflector, either at the first end, the side walls or both, may be selected such that back scattered radiation which, before entering the waveguide, at angles nearer perpendicular to the patient's skin are reflected more strongly than backscattered radiation which, before entering the waveguide, are at angles more nearly parallel to the skin surface. The second end of the waveguide in contact with the patient's skin may also have an aperture which is at least substantially as great as the aperture of radiation back-scattered from the patient's skin or a "reflection aperture" substantially as great as the radiation back-scatter aperture may be achieved in other ways. For example, a reflector plate of size to provide the desired reflection aperture may surround the second end of the waveguide. More generally, the invention may include at least one waveguide passing through the head and terminating at a skin-contacting surface

thereof, EM radiation being applied through the at least waveguide path to the patient's skin; and a reflection means for returning back-scattered radiation to the patient's skin, which reflection means has a reflection aperture at least substantially as great as the radiation back-scatter aperture. Reflection means may include at least a portion of the skin-contacting surface of the head, which portion may be in the form of a reflection plate, and may also include at least one reflection surface for back-scattered radiation entering the waveguide, at least part of which surface may be in the waveguide.

The system may be for treating a selected dermatological problem in a selected volume of a patient's skin at a depth d which is below the DE junction. A source of EM radiation of a wavelength appropriate for treating the problem is provided along with an optical waveguide, a mechanism which cools the patient's skin, at least in the portion thereof in contact with the waveguide when the second end of the waveguide is in contact with the patient's skin, and a temperature sensor at the second end of the waveguide. The temperature at the sensor is indicative of the temperature at the patient's DE junction. Finally, controls are provided which are operative in response to the sensor indicating that the DE junction has been cooled to at least a selected temperature for permitting radiation from the source to be passed through the waveguide to the patient's skin. The cooling mechanism preferably removes heat from the waveguide; when in contact with the patient's skin, the waveguide removing heat from and thus cooling the skin. The controls may also be operative in response to the sensor for maintaining the DE junction within a selected temperature range during application of radiation to the patient's skin. The controls may also detect a selected temperature/time profile at the sensor, the profile being indicative of contact of the waveguide with the patient's skin, and may prevent radiation from passing to the patient's skin unless the predetermined profile is detected. This assures that radiation is not applied to the patient's skin unless there is good thermal contact between the radiation-applying waveguide of the head and the patient's skin. For preferred embodiments, the controls operate the cooling mechanism to cool the waveguide to a desired temperature, the controls being responsive to the sensor for determining when the desired temperature has been reached.

The controls may also be operative in response to the sensor sensing a selected increasing temperature profile at the sensor when the waveguide is placed in contact with the patient's skin for permitting radiation from the source to be passed through the waveguide to the patient's skin.

This control may be instead of the control based on detection that the DE junction has been cooled to a selected temperature, but is preferably in addition thereto.

The enhanced retro-reflector features discussed above may also be used in the head independent of the temperature measuring features previously discussed, but are preferably used in conjunction therewith. The invention may also include a head having at least one optical waveguide for receiving EM radiation and for directing it to a skin-contacting surface of the at least one waveguide and a standoff having a first and a second end, with the first end surrounding the at least one waveguide at its lower end and forming a substantially air-tight seal therewith. The second end of the standoff is adapted to be in contact with the patient's skin over the selected volume to form a chamber between the skin-contacting waveguide surface, the patient's skin and walls of the standoff. A means is also provided for creating negative pressure in the chamber to draw the patient's skin therein and into contact with the skin-contact surface. The walls of the standoff are preferable reflective to return back-scattered radiation to the patient's skin. The means for creating negative pressure may include a hose mounted at one end to open into the chamber and connected at its other end to a source of negative pressure. Alternatively, the means for creating negative pressure may include the walls of the standoff being deformable when pressure is applied to the head/waveguide to permit the skin-contacting surface of the waveguide to contact the patient's skin, forcing most of the air from the chamber, with the walls of the standoff returning to the their undeformed state when pressure is released, resulting in the creation of negative pressure in the chamber. For example, the walls of the standoff may be in the form of a bellows, suction cup or elastic ring.

Finally, rather than a single optical waveguide, the output surface of a first optical waveguide to which irradiation is initially applied may be mounted to a first surface of a second optical waveguide which also has a second skin-contacting surface opposite the first surface. Optical radiation received from the first waveguide is transmitted through the second waveguide to the skin-contacting surface thereof. The second skin-contacting surface of the second waveguide has a larger area than the output surface of the first waveguide and the second waveguide is formed to provide a larger optical aperture than of the first waveguide. The ratio of the spacing between the first and second surfaces of the second waveguide and a selected surface dimension of the skin-contacting surface of the second waveguide, for example the length of a side of the second surface or a diameter thereof, is approximately 1.5 to 1. Means may be provided for reflecting radiation back-scattered from the patient's skin into the second waveguide

back into the patient's skin. The means for reflecting may include forming at least a portion of the first surface and/or other surfaces of the second waveguide so as to reflect radiation impinging thereon, and such reflection from the second waveguide may also be made angle dependent.

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention as illustrated in the accompanying drawings.

In the Drawings

Fig. 1 is a schematic semi-block diagram of a simplified EM radiation treatment system suitable for use in practicing the teachings of this invention.

Fig. 2 is a side sectional view of a head or applicator suitable for use in the system of Fig. 1 in accordance with teachings of this invention.

Fig. 3a is a graph illustrating a calculated relationship over time between the temperature at the waveguide at two Δd 's where a sensor may be located and the temperature at three different depths in a patient's skin, including at the DE or basal junction.

Fig. 3b is a graph illustrating a measured relationship over time between the temperature at the waveguide sensor for a preferred Δd and the temperature at two different depths in a patient's skin, including at the DE or basal junction.

Fig. 4 is a graph illustrating temperature sensor output over time for selected conditions.

Figs. 5a and 5b are simplified side sectional views of two alternative heads or applicators for providing a reflection aperture matching the aperture of radiation back-scatter.

Figs. 6a and 6b are simplified side sectional views of a head or applicator which utilizes negative pressure to draw a fold of skin into a cavity before negative pressure is applied and after negative pressure is applied respectively.

Figs. 7a and 7b are simplified side sectional views of a head or applicator for another embodiment of the invention which utilizes negative pressure to draw a fold of skin into a cavity at an intermediate step in the creation of the negative pressure and after negative pressure has been created respectively.

Figs. 8a, 8b and 8c are simplified side sectional views of a head or applicator for still another embodiment which uses negative pressure to draw a fold of skin into a chamber shown before negative pressure is created, at an intermediate stage in the creation of negative pressure and after negative pressure has been created respectively.

Fig. 9 is a simplified side sectional view of a head for an alternative embodiment of the invention which provides an expanded optical aperture for the head.

Fig. 10 is a simplified side sectional view of a head for an alternative embodiment which head is suitable for moving across a patient's skin during treatment.

Detailed Description

Fig. 1 is a simplified block diagram of a system 10 which may be utilized for treating a selected dermatological condition in accordance with the teachings of this invention. The system includes an electromagnetic (EM) radiation source 12 which is connected through a fiber optic light pipe or other suitable optical conveyor 14 to an applicator or head 16, which head is in contact with the skin 18 of a patient. Controls 20 are provided which receive information from source 12 and head 16 and which control operation of the system in response to these inputs and others. EM source 12 may be a ruby laser, alexandrite laser, diode laser or other laser source providing radiation of a suitable wavelength for the laser treatment to be performed, or may be a lamp or other non-coherent electromagnetic radiation source providing signals at the requisite wavelength. Particularly for non-coherent light sources, various techniques may be utilized to filter, frequency shift or otherwise control the output from the source to achieve radiation within a desired wavelength band. The radiation wavelength may be narrow band, down to a single wavelength, or wide band, and may vary over a wide spectrum from infrared through ultraviolet, depending on the treatment to be performed and the radiation source utilized. Source 12 may be a pulsed source, either under operator control or at a fixed or controlled repetition rate, or may, as taught in copending applications Serial No. 09/078,055, be a continuous wave (CW) source. Controls 20 may be a suitably programmed general purpose or special purpose computer, may be hard wired circuitry, or may be a hybrid of special purpose circuitry and programmed computer circuitry. Skin 18 has an epidermal layer 22, and a dermal layer 24, the junction of these two layers being sometimes referred to as the DE junction or basal layer 26.

Radiation from source 12 passes through head 16 and is emitted therefrom as a converging beam 28 which is applied to an area 30 in dermis 24 containing the element to be treated. Area 30 may, for example, contain a hair follicle which is to be destroyed in order to achieve removal of unwanted hair, may be tattoo pigment which is to be removed, may be a spider vein or other blood vessel which is to be coagulated and removed or may be some other dermatological condition which is to be treated by the radiation. As discussed earlier, treatment

of a patient is complicated by the fact that there may be significant variations among patients, and in different areas of the body of the same patient, in the thickness of epidermal layer 22, in the pigmentation of this layer (and in particular in the quantity of melanin at DE junction 26), and in other characteristics of the skin. These variations make it difficult to achieve a desired therapeutic effect without potential damage to the area of the patient's epidermis overlying treatment area 30.

Fig. 2 illustrates a head 16 suitable for use in the system of Fig. 1. Referring to Fig. 2, head 16 includes a waveguide or lens 40 of an optically transparent material which also has good heat transfer properties and preferably provides a good index of refraction match with skin. Sapphire is a currently preferred material for the waveguide, although other materials could also be used. Waveguide 40 is supported by a holder ring 42 mounted in an exterior housing 44. A thermocouple, thermistor or other suitable temperature sensor 46 is mounted in contact with waveguide 40, between the waveguide and holder 42. The distance (Δd) of sensor 46 from the end of waveguide 40 in contact with the patient's skin is critical and, for reasons to be discussed later, should be no more than 5 mm. Δd is preferably in the 1-2 mm range, with approximately 1 mm being the currently preferred distance. While a single temperature sensor 46 is shown in Fig. 2, two or more such sensors spaced around waveguide 40 at the same distance Δd from the end of the waveguide may be preferable to average out temperature variations which may occur in the waveguide.

Thermoelectric cooling elements 48 are also provided in contact with waveguide 40. While two such elements are shown in Fig. 2, typically at least four such elements, substantially evenly spaced around the periphery of waveguide 40, would normally be provided. Thermoelectric elements 48 may for example be Peltier elements. Electrical connections are made to sensor(s) 46 and to thermoelectric elements 48 in a manner known in the art and to simplify the figure are not specifically shown therein.

The sides of thermoelectric elements 48 opposite those in contact with waveguide 40 are in thermal contact with heat sink or radiator 50 having channels 52 formed therein through which a cooling fluid such as air or water flows, the cooling fluid entering the head through a fluid junction 54 and exiting through a fluid junction 56 (or entering through fluid junction 56 and exiting through fluid junction 54).

Optical radiation is applied to the head through an optical fiber, fiber bundle or other light pipe 58 which terminates at a chamber 60. Radiation exiting optical fiber 58 expands in chamber

60 before entering waveguide 40 for application to the patient's skin. Fiber 58 is mounted in a sleeve 62 of optically opaque material, the rear portion of which is mounted in a tube 64 and the forward portion of which extends through a holder assembly 66. Tube 64 is mounted in a chamber 68 formed in the rear of holder assembly 66 to permit assembly 69, which includes fiber
5 58, sleeve 62 and tube 64, to be moved forward and backward, moving fiber 58 in chamber 60 to adjust the optical aperture of the head. O-rings 70 and 72 seal chamber 60 to keep air and moisture out so as to avoid condensation on cooled optical surfaces 74 and 76. Nitrogen or another gas which does not condense at temperatures down to -40°C is utilized to fill chamber 60.

10 Surface 74 of the waveguide is an optical reflecting surface as are all surfaces of chamber 60, including surface 76 at the rear thereof. As will be discussed later, these surfaces retroreflect back-scattered light from the patient's skin. The side walls of both waveguide 40 and chamber 60 may also be fully reflective or may selectively reflect in a manner and for reasons to be discussed later.

15 In operation, assembly 69 is initially positioned to achieve a desired optical aperture for head 16. Thermoelectric elements 48 are also energized to cool waveguide 40 to a selected temperature, for example 10°C to -40°C. The criteria is to bring the waveguide 40 to a sufficiently low temperature to achieve the desired cooling of epidermis 22 without resulting in tissue temperature being brought down to a level where water in the cells might freeze. Good
20 results have been achieved with a waveguide temperature in the 0°C to -30°C range, with a preferred temperature of approximately -10°C.

When the above preliminary steps have been completed, head 16 may be brought into physical contact with an area of the patient's skin where treatment is to be performed. This contact may be under low pressure, preferably at least sufficient to establish good thermal contact
25 between waveguide 40 and the patient's skin, where the objective is to coagulate blood in for example a spider vein, leg vein or other vein or blood vessel, or may be under pressure greater than the patient's blood pressure for hair removal or other applications where it is preferable to remove blood from the region of skin between waveguide 40 and area 30 under treatment.

30 In any event, head 16, and in particular waveguide 40 thereof, should be placed in contact with the patient's skin with sufficient pressure to assure good thermal contact between the patient's skin and waveguide 40. In accordance with the teachings of this invention, the fact that such good thermal contact has been established can be detected through use of sensor 46. In

particular, as seen in Figs. 3a and 3b, with the sensor positioned approximately 1 mm from the contact surface of waveguide 40, (i.e. $\Delta d = 1$ mm), the temperature at the sensor has a profile 90 in Fig. 3a and 90' in Fig. 3b which increases sharply for the first quarter to one-half second after such thermal contact has been established. The reason for this is that the waveguide is acting as a heat sink for the patient's skin during this time interval and the heating of the waveguide at the skin-contacting end thereof is greater than the cooling effect of thermoelectric device 48 at this surface (i.e. there is a small temperature gradient across waveguide 40). The detection of the temperature profile 90, 90' by sensor(s) 46 can be interpreted by controls 20 as an indication of good thermal contact between the waveguide and the patient's skin. If such a thermal profile is not detected, controls 20 inhibit the activation of radiation source 12 and/or prevent radiation from the source being applied to head 16. This assures that radiation is not delivered to the skin unless the epidermis has been adequately cooled to prevent thermal damage thereto.

Referring for example to Fig. 3a, it is seen that the placement of sensor 46 relative to the skin-contacting surface of waveguide 40, or in other words the distance Δd , is critical in order to achieve this objective. In particular, while profile 90 is achieved for a Δd of approximately 1.2 mm, profile 91, which is achieved with a Δd of approximately 4.8 mm, evidences far less sensitivity to temperature changes at the DE junction and is therefore not particularly useful in assuring good thermal contact between the waveguide and the patient's skin. Actual profile 90' (Fig. 3b), while slightly more stepped and less smooth than the theoretical profile 90 of Fig. 3a, is sufficiently similar to this profile so as to permit easy identification of good thermal contact. Differences between Figs. 3a and 3b may also arise from the fact that the waveguide in Fig. 3a starts at a temperature of -10°C while the waveguide in Fig. 3b starts at a temperature of approximately -27°C .

Referring again to the Figures, and in particular to Fig. 3a, it is seen that a major portion of the waveguide cooling occurs within a period of between 0.5 and 2 seconds from full contact, the time varying somewhat with the initial temperature of the waveguide and the desired final temperature at the DE junction. Therefore, assuming good thermal contact has been made, an operator may operate source 12 some predetermined time after making contact with the patient's skin, for example a half second thereafter, but not more than approximately 2 seconds thereafter, to avoid significant cooling of the dermis.

However, since cooling of the skin may vary depending on a number of factors, including variations in the equipment being utilized, the color and nature of the patient's skin, the thickness

of the patient's skin and the like, it is preferable that the temperature at the DE junction be measured and that the radiation source 12 be operated as soon as this temperature has dropped to a desired level. As can be seen from Figs. 3a and 3b, the temperature profile 90 at sensor 46 tracks the temperature profile 92 at the DE junction as does the temperature profile 90' for DE junction temperature profile 92'. Thus, the output from sensor 46 can be utilized by control 20 as an indication of temperature at the DE junction, and radiation source 12 can be operated by control 20 when this temperature reaches a predetermined value. This assures that radiation is not applied to the patient until the patient's epidermis has been fully cooled to the desired level and that the operation of laser source 12 is not delayed so long as to cause cooling of portions of the follicle which are to be destroyed. In particular, 94 is a profile taken approximately 1 mm from the surface of the patient's skin, which is approximately the depth of the bulge in a hair follicle, and may be a depth where other dermatological treatments such as tattoo removal, treatment of port wine stain or vascular lesions may occur. From Fig. 3a it is seen that for a time over two seconds, there is a significant drop in temperature at this depth, which can be 10°C or more. For many dermatological applications, such a drop in temperature 1 mm into the dermis is undesirable, and in particular can adversely affect the desired treatment. Curves 96, 96' are temperature profiles with time deeper into the dermis, for example 2 mm therein. At this depth, the cooling effect of cooled waveguide 40 is not significant, perhaps a few degrees Celsius. This lack of cooling effect at deeper depths stems both from the greater distance of these point from the cooling source and from the proximity of tissue at this depth to the warming effect of blood-carrying vessels. The teachings of this invention thus permit and assure that the radiation source is not operated to cause heating of the patient's epidermis until the epidermis has been cooled to the desired depth and temperature, but that firing of the radiation source occurs before there is any significant cooling of the dermis. The invention further permits these controls to be performed completely automatically, thereby reducing the skill level required to safely perform such dermatological procedures, and permitting such procedures to be performed by less skilled and therefore less expensive personnel.

During the firing of the radiation source, control 20 continues to monitor the temperature at sensor 46. If at any time during the firing of the radiation source, there is an increase in temperature at sensor 46 which deviates from what would be anticipated from profile 90, controls 20 can immediately turn off the source 12 to prevent any thermal damage to the patient's epidermis 22.

While for certain treatments, the system of this invention may be able to detect successful completion of the treatment, this is not easy to do, particularly for treatments being performed several millimeters into the dermis. The radiation source is therefore typically fired for a predetermined time interval and/or head 16 is maintained in contact with the patient's skin for a predetermined time interval. Control 20 may determine when such time interval has expired, turn off source 12 when such time period has passed and perhaps generate an audio or visual indication to the operator to remove head 16 from the patient's skin. These steps also reduce the skill level required for using the system.

As indicated earlier, one problem with utilizing radiation to treat dermatological conditions is that a significant portion of the radiation applied to the patient's skin is back-scattered and lost, therefore increasing the power required from the radiation source utilized, and thus the cost of the system. One solution to this problem is to efficiently collect radiation back-scattered from the patient's skin and to reflect such radiation back into the patient's skin with minimum loss. Fig. 2 shows a retroreflector which is particularly well suited for performing this function. In particular, waveguide 40 has an aperture which is larger than the optical aperture of the radiation applied to the patient's skin and which is instead substantially equal to the aperture of radiation back-scattered from the patient's skin. Thus, substantially all of the back-scattered radiation is collected in waveguide 40. Waveguide 40 has an external coating or is otherwise designed in manners known in the art so as to totally internally reflect the back-scattered radiation collected therein. Some of such radiation impinges on reflecting surface 74 and is returned through the totally internally reflecting waveguide from such surface to the patient's skin. The remainder of the back-scattered radiation extends into chamber 60 which is also totally internally reflected and ultimately impinges on reflecting surface 76 which returns this radiation with minimal loss to the patient's skin. Thus, the retroreflective design for the head 16 in Fig. 2 results in the collection and retroreflection back into the skin of substantially all back-scattered radiation.

In the discussion above, the side walls and back walls of both waveguide 40 and chamber 60 are fully reflecting so that substantially all of the light retroreflected into waveguide 40 is returned to the patient's skin. However, since radiation entering the waveguide from the skin (before refraction on entering the waveguide), is retroreflected back into the patient's skin at substantially the same angle, such radiation at relatively sharp angles, (i.e., at angles more nearly parallel to the patient's skin than perpendicular) contributes primarily to heating the patient's epidermis, potentially causing thermal damage thereto, without reaching region 30, and therefore

without having any therapeutic effect. It is therefore preferable that such sharply angled radiation not be retroreflected or that, as a minimum, the retroreflection of such radiation be substantially attenuated. This can be accomplished in the embodiment of Fig. 2 by for example utilizing an angle dependent coating for the side walls of waveguide 40, the rear wall of waveguide 40, or both so that these walls of the waveguide either do not reflect or minimally reflect large angle radiation entering the waveguide, while more strongly reflecting radiation coming in at a more closely perpendicular angle. Alternatively, the side wall may have varying coefficients of reflection, being less reflective for the portions of the wall closest to the tip or skin contacting surface of waveguide 40 and more reflective toward the rear of the waveguide. Other techniques could also be utilized to assure that waveguide 40 and chamber 60 more strongly reflect retroreflected radiation applied thereto at an angle more nearly perpendicular to the skin surface than radiation applied thereto at an angle more nearly parallel to the skin surface, the perpendicular radiation being substantially fully retroreflected, while the parallel radiation is substantially attenuated.

Fig. 4 illustrates the voltage output at sensor 46 as a function of time under selected operating conditions. The solid line 93 illustrates a representative output when the waveguide 40 of head 16 is placed in contact with a patient's skin at time t_1 . From time t_1 to time t_2 the temperature at the sensor increases as the skin in contact with waveguide 40 is cooled. At time t_2 , source 12 is operating to apply a radiation pulse through the waveguide to the patient's skin causing an increase in the temperature of the patient's skin which is reflected as a spike in the voltage output from the temperature sensor 46. The temperature then decreases rapidly until just before a time t_3 when backscattered radiation from the patient's skin starts to be received in the waveguide. The time between t_2 and t_3 is a function of the thickness of the patient's epidermis to the DE junction where melanin is being heated and the amplitude of the spike at time t_3 is a function the patient's skin type, more energy being reflected for a patient having darker skin, for example spike 95, than for patients having lighter skin. Thus, the amplitude of the spike which occurs at time t_3 may be utilized as an indication of the patient's skin type, and this information may be reviewed at least periodically by the system controls, since skin type will vary even for a given patient as different areas of the patient's skin are being treated.

Patient's skin type may also be determined by taking two successive readings, one with head 16 not in contact with the patient's skin and a second with the head in contact with the patient's skin. Curve 93 is an example of the output which is obtained when the head is in

contact with the patient's skin, while curve 97 which would start at time t_2 , is indicative of an output which would be obtained when the laser is fired at time t_2 with the head not in contact with the patient's skin. Since the output in air is proportional to the coefficient of absorption for air times the applied laser energy ($V_A = k_0 E$) and V_s when the head is in contact with the patient's skin

5 is given by

$$V_s = k_0 E + k_0 R E$$

where R is the coefficient of reflection from the patient's skin, $R = (V_s - V_a / k_0 E)$. Since k_0 and E are known values, the difference in voltage for the two readings provides a reliable indication of the coefficient of reflection from the patient's skin in the area under treatment, or in other words of the patient's skin type. The output from temperature sensor 46 may also be utilized for other

10 purposes.

Fig. 5a shows an alternative embodiment of the invention for performing the retroreflector function where the surface area or aperture of waveguide 40 is substantially equal to the optical aperture of radiation applied to the patient's skin. It is therefore smaller than the aperture D of radiation back-scattered from the patient's skin. Therefore, a reflector plate 97 is provided, which

15 may be a specular or diffuse reflector. Plate 97 has a hole which is sized and shaped to permit waveguide 40 to fit therein. Plate 97 may, for example, extend for approximately 1 to 6 millimeters on either side of waveguide 40, but this dimension will vary with application, and can be outside the above range for selected applications. The reflective effect can be enhanced by providing a liquid or other reflective index-matching substance 98 between the skin 18 and

20 the waveguide 40/plate 97, which substance has a reflective index equal or greater than the reflective index of the skin. This decreases the total internal reflection from the skin surface, allowing better return of radiation into the deep layers of skin by reflector 97. Thermoelectric elements 99 in contact with reflective plate 97, which may be formed of a material having good thermal conducting properties such as metal, can be utilized to heat plate 97 to a temperature of,

25 for example, 45-50 C°. Plate 97 can thus preheat the area of the patient's skin surrounding the area where radiation is to be applied, thereby increasing the temperature at the treatment area in the dermis, and thus decreasing the light energy required for performing the desired treatment.

Fig. 5b illustrates an alternative embodiment wherein the reflector 97' has an enhanced efficiency by being formed in a cone or other concave shape. This results in the back-scattered

30 light reflected into the skin being concentrated in the region of the radiation or collimated beam

delivered into the skin through waveguide 40, thus increasing the quantity of radiation delivered to the treatment area. Except for the shape of the reflection plate 97', the embodiment of Fig. 5b otherwise functions in the same way as the embodiment of Fig. 5a. As for the embodiment of Fig. 2, retroreflection from waveguide 40 can be angle dependent for the embodiments of Fig. 5a and 5b and, particularly for the embodiment of Fig. 5a, reflection from plate 97 can also be made angle dependent by suitably coating the reflecting surface thereof.

Fig. 6a and 6b show another embodiment of the invention which differs from those previously described in that reflection plate 97" is even more angled than for the embodiment of Fig. 5 and is generally in the form of a truncated cone which is secured to the lower end of waveguide 40 in a manner so as to form a substantially air-tight seal therewith. Such securing may be by providing a pressure fit between plate 97" and waveguide 40, but is preferably achieved by applying a suitable adhesive between the two components. Another alternative would be to have some form of screw thread formed in or on waveguide 40 which mates with a corresponding tread on plate 97", but such tread might interfere with the optical properties of waveguide 40. A hose 100 passes between plate 97" and waveguide 40 and is sealed therebetween, hose 100 being attached to a source of negative pressure (for example vacuum pressure) (not shown). As may be best seen in Fig. 6a, when head 16 of this embodiment is pressed against skin 16, a chamber 99 is formed which is defined by the light reflecting walls of plate 97", the lower surface of waveguide 40, and the surface of the patient's skin 18 which is inside the cone of plate 97". Plate 97" will sometimes also be referred to hereinafter as a standoff.

In operation, once head 16 is in the position shown in Fig. 6a, vacuum is applied through hose 100 to chamber 99 to remove air therefrom. This has the effect of drawing a portion or fold 105 of the patient's skin into chamber 99 and into contact with the lower skin-contacting surface of waveguide 40. This can reduce the distance between waveguide 40 and the target volume in skin portion 105 at which treatment is desired and also brings this target volume into chamber 60 where back-scattered radiation retroreflected from the reflecting walls of plate 97" concentrate this radiation on the target volume. This reduces the amount of energy required from EM source 12 and significantly enhances the overall efficiency of the system. The depth of chamber 99 from the bottom of waveguide 40 to the skin surface would typically be in the 5 mm range and should normally not be more than approximately 10 mm. The diameter D of standoff or plate 97" at the skin-contacting end thereof is, as for the embodiment of Figs. 5a and 5b substantially equal to the aperture of back-scatter radiation.

Fig. 7 shows and embodiment of the invention which differs from that shown in Fig. 6 in that, instead of a vacuum line 100 being utilized to obtain reduced or vacuum pressure in chamber 99, standoff 101 is in the form of a bellows which collapses when head 16 is pressed against the skin as shown in Fig. 7a forcing air out of chamber 99. When pressure on head 16 is removed, or if slight upward pressure is applied to the head, bellows 101 straightens as shown in Fig. 7b. The vacuum in chamber 99 holds bellows 101 against the skin resulting in skin fold 105 again being drawn into chamber 99 as bellows 101 returns to its normal position. The embodiment of Fig. 7 functions substantially the same as the embodiment of Fig. 6 with the inside of bellows 101 having a reflective coating or otherwise being reflective. While the base of bellows or standoff 101 has only a slightly larger aperture than the aperture d of waveguide 40, this is not a problem since substantially all of the back-scattered radiation from the skin is emitted into chamber 99 where it is reflected in a concentrated manner back to the target volume and there should be virtually no back-scattered radiation outside of chamber 99. Sharply angled radiation is also productively utilized for these embodiments. An effect substantially the same as that of Fig. 7 can be achieved by using a standoff in the form of a suction cup in lieu of the standoff's 97" or 101 as shown.

Figs. 8a-8c shows still another embodiment of the invention which differs from that shown in Fig. 7 in that a ring 102 of an elastic material is substituted for the bellows 101. When ring 102 is pressed against the skin as shown in Fig. 8b, the ring deforms permitting waveguide 40 to move substantially into contact with skin 18 as air is forced out of chamber 99. When the pressure is released, elastic ring 102 returns to the condition shown in Fig. 8c, resulting in skin fold 105 being drawn into the chamber as shown.

While three standoff configurations have been shown and/or described above for achieving vacuum pressure, or at least negative pressure, in chamber 99 by collapsing a standoff and then permitting it to return to its normal position, the embodiments shown and/or described are by way of illustration only, and other standoff configurations for achieving the same objective might also be utilized. Further, in addition to the use of vacuum hose 100 as shown in Fig. 6, other methods known in the art may be used for achieving the desired reduced pressure in chambers 99 so as to cause a fold of skin 105 to be drawn therein for irradiation.

Fig. 9 shows still another embodiment of the invention which differs from those previously shown in that, rather than a bottom surface of waveguide 40 being in contact with the patient's skin 18, the lower end of waveguide 40 is in contact with a second waveguide 103 which

is preferably of sapphire or other material having good optical and thermal conduction properties. Sapphire is particularly preferred, because it also provides a fairly good optical index match with skin. Index matching material 98 may be utilized between waveguide 103 and the patient's skin to further enhance this match. While not specifically shown in Fig. 9, waveguide 103 would also have, for preferred embodiments, one or more temperature sensors 46 positioned close to its skin-contacting surface and one or more thermoelectric elements 48 or other temperature control elements in contact therewith to preheat and/or cool the patient's skin 18 as required. A reflective coating 104 may also be provided on the rear surface of waveguide 103 to, in conjunction with the retroreflector previously described for waveguide 40, retroreflect substantially all radiation back-scattered from the patient's skin. Angle dependent retroreflection might also be employed for this embodiment using techniques previously discussed, such angle dependent retroreflection occurring at least for waveguide 103, and preferably for both waveguides. The advantage of the embodiment shown in Fig. 9 is that it significantly enlarges the optical aperture for treatment, permitting treatment over a relatively large area, for example hair removal over a patient's legs or back, to be accomplished far more rapidly than when a head having a smaller aperture is utilized. The skin-contacting surface of waveguide 103 may have a variety of shapes, and may for example be circular or square. A circular waveguide 103 might for example have a diameter of approximately 1 inch while a square waveguide 103 might have sides 2 cm long, the height of waveguide 103 preferable being roughly 1.5 times this dimension. These dimensions are, however, being provided by way of illustration only and the specific dimensions of waveguide 103 will vary with application.

In the discussion to this point, it has been assumed that the head utilized is applied to a point on a patient's skin where treatment is to be performed and that, after a suitable period of time has passed for cooling of the skin to the DE junction to have occurred, an optical radiation pulse, for example a laser pulse, is applied through the waveguide to treatment area 30. Fig. 10 shows an embodiment of the invention which, like the embodiments taught in application Serial No. 09/078,055, is intended to be in contact with the patient's skin 18 and to be moved in direction 112 over the skin while remaining in contact therewith. Radiation applied to waveguides light paths 114 in this head may be continuous wave or may be pulsed at a high enough rate to permit movement of the head over the treatment area. For the embodiment shown in Fig. 10, the head has an area 116 ahead of waveguides 114 which passes over the treatment area before radiation is applied thereto. Region 116 is preferably of a thermally conductive

material and is insulated from a second region 118 of the head, which is preferably also of a thermally conductive material, by a thermally insulating layer 120. A thermal electric element or other suitable heater/chiller 122 is in contact with portion 116 and may be used to either preheat or precool the treatment area. For example, if element 122 is a heater, it can heat the skin down to region 30 to a temperature below that at which thermal damage would occur. Further, a temperature sensor 124 is provided, for example up to 5 mm from the skin contacting surface (and preferably less, i.e., to 1 to 2 mm) to indicate skin temperature at for example the DE junction. Sensor 124, by detecting the heating of melanin in the epidermis provides an indication of skin type for the patient, which indication can be used to control the radiation applied. It also assures that overheating in the epidermis does not occur. A thermal electric element or other suitable cooler 126 connected to region 118 cools the epidermis ahead of waveguides 114 coming over a treatment area. A temperature sensor 128 can also be provided in region 118, for example up to 5 mm from the skin contacting surface, to assure that this region has cooled sufficiently before radiation is applied thereto and to protect against thermal damage to this region. While a single pair of waveguides 114 are shown in Fig. 10, typically a plurality of such waveguides would be stacked adjacent to each other in a direction into the figure. Two or more heaters/chillers 122, 126 could also be provided and two or more sensors 124, 128 could also be provided. Further, the sensor technology of this invention could also be utilized with other ones of the embodiments shown in application Serial No. 09/078,055.

While the invention has been described above with reference to a particular system 10 and to particular head designs 16, neither are limitations on the invention. In particular, other techniques known in the art, for example circulating water or air, could be utilized for cooling waveguide 40 in lieu of thermoelectronic cooling elements 48, although such thermoelectronic cooling elements are at this time preferred. Some elements 48 (or other thermal control elements) might also be used to heat waveguide 40 to preheat the target area, after which either the same or different thermal control elements would be used to cool the waveguide as previously indicated to cool the patient's epidermis in the treatment area. A lens may also be substituted for waveguide 40, although waveguide 40 is currently preferred because of its superior thermal properties and its superior performance in retroreflection. Other light guiding/transmitting element may also be used and, in some applications, two or more such elements may be used as shown in Fig. 10, rather than a single element to transmit EM radiation through the head to the patient's skin. Other details of construction for head 16 or head 110 may also be varied.

depending on application. Thus, while the invention has been particularly shown and described above with reference to preferred embodiments, the foregoing and other changes in form and detail may be made therein by one skilled in the art while still remaining within spirit and scope of the invention which is to be defined only by the appended claims.

Claims

1. A head for applying EM radiation of a wavelength appropriate for treating a selected patient dermatologic problem to a selected volume of a patient's skin, the volume containing the
5 problem to be treated, the head including:
an optical waveguide;
a light path for directing the EM radiation to a first end of the waveguide, said waveguide having a skin-contacting second end which is opposite said first end; and
a sensor at said second end of the waveguide which senses the temperature thereat.
10
2. A head as claimed in claim 1 wherein said sensor is located no more than a few millimeters from the second end of the waveguide.
3. A head as claimed in claim 2 wherein said sensor is located within 5 millimeters of said
15 second end of the waveguide.
4. A head as claimed in claim 2 wherein said sensor is located within 2 millimeters of said second end of the waveguide.
- 20 5. A head as claimed in claim 2 wherein said sensor is located within 1 millimeter of said second end of the waveguide.
6. A head as claimed in claim 1 including a mechanism for removing heat from the waveguide.
25
7. A head as claimed in claim 6 wherein said mechanism includes a thermoelectric device having one side in thermal contact with said waveguide and an opposite side in thermal contact with a temperature sink.
- 30 8. A head as claimed in claim 1 wherein said head has a reflection aperture at a skin-contacting end thereof at least substantially as great as the aperture of radiation back-scattered from the patient's skin.

9. A head as claimed in claim 8 wherein said second end of the waveguide has an aperture at least substantially as great as the aperture of radiation back-scattered from the patient's skin.

10. A head as claimed in claim 8 wherein at least part of the back-scattered radiation enters
5 said waveguide and is substantially internally reflected within said waveguide; and
including a reflector within said waveguide for returning back-scattered radiation through
the waveguide to the patient's skin.

11. A head as claimed in claim 10 wherein said reflector is at said first end of the waveguide.

10

12. A head as claimed in claim 11 wherein said reflector is also along at least a portion of
waveguide sidewalls, and wherein said reflector has a coefficient of reflection at areas thereof
such that backscattered radiation at angles nearer perpendicular to said skin contacting second
end are reflected more strongly than back scattered radiation at angles nearer parallel to said
15 second end.

13. A head as claimed in claim 8 including a reflector plate surrounding said waveguide at
the second end thereof, the combined area of the plate and the waveguide projecting therethrough
being substantially equal to the aperture of radiation back-scatter.

20

14. A head as claimed in claim 13 wherein said plate has a concave shape.

15. A head as claimed in claim 13 including a means for controlling the temperature of the
plate.

25

16. A system for treating a selected dermatologic problem located in a selected volume of a
patient's skin at a depth d , which depth is below the DE junction, comprising:

a source of EM radiation of a wavelength appropriate for treating said problem;

an optical waveguide having a first end at which said radiation is applied and a second
30 end for contacting the patient's skin, which second end is opposite said first end;

a temperature sensor at said second end of the waveguide, the temperature at said sensor
being indicative of the temperature at a selected depth within the patient's skin;

a mechanism which removes heat from the patient's skin at least in the area thereof in contact with said waveguide; and

controls operative in response to said sensor indicating that the patient's skin at said selected depth has been cooled to at least a selected temperature for permitting radiation from said source to be passed through said waveguide to the patient's skin, including said selected volume.

17. A system as claimed in claim 16 wherein said mechanism removes heat from the waveguide, the waveguide, when in contact with the skin, removing heat from, and thus cooling, the skin.

18. A system as claimed in claim 17 wherein said selected depth is the DE junction, and wherein said controls are operative in responsive to said sensor for maintaining the DE junction within a selected temperature range during application of said radiation to the patient's skin.

19. A system as claimed in claim 17 wherein said controls detect a temperature profile at said sensor, said profile being indicative of contact of said waveguide with the patient's skin, and wherein said controls prevent said radiation from passing to the patient's skin unless a predetermined profile is detected.

20. A system as claimed in claim 17 wherein said controls operate said mechanism to cool said waveguide to a desired temperature, and wherein said controls are responsive to said sensor for determining when said temperature has been reached.

21. A system as claimed in claim 16 wherein said sensor is located no more than a few millimeters from the second end of said waveguide.

22. A system as claimed in claim 16 wherein said second end of the waveguide has an aperture at least substantially as great as the aperture of radiation back-scattered from the patient's skin.

23. A system as claimed in claim 22 wherein back-scattered radiation is substantially internally reflected within said waveguide; and

including a reflector within said waveguide for returning back-scattered radiation through the waveguide to the patient's skin.

5

24. A system as claimed in claim 23 wherein said reflector is at said first end of the waveguide.

25. A system as claimed in claim 24 wherein said reflector is also along at least a portion of waveguide sidewalls, and wherein said reflector has a coefficient of reflection at areas thereof such that backscattered radiation at angles nearer perpendicular to said skin contacting second end are reflected more strongly than back scattered radiation at angles nearer parallel to said second end.

15 26. A system for treating a selected dermatologic problem located in a selected volume of a patient's skin at a depth d, which depth is below the DE junction, comprising:

a source of EM radiation of a wavelength appropriate for treating said problem;

an optical waveguide having a first end at which said radiation is applied and a second end for contacting the patient's skin, which second end is opposite said first end;

20 a mechanism which cools the patient's skin, at least in the portion thereof in contact with said waveguide, when said second end is in contact with the patient's skin;

a temperature sensor at said second end of the waveguide, the temperature at said sensor being indicative of the temperature at the patient's DE junction; and

controls operative in response the sensor sensing a selected increasing temperature profile at the sensor when the waveguide is placed in contact with the patient's skin for permitting radiation from said source to be passed through said waveguide to the patient's skin, including said selected volume.

27. A system as for treating a selected dermatologic problem located in a selected volume of a patient's skin, comprising:

30 a source of EM radiation of a wavelength appropriate for treating said problem;

an optical waveguide having a first end at which said radiation is applied and a second end for contacting the patient's skin, which second end is opposite said first end;

controls for selectively permitting radiation from said source to be passed through said waveguide to the patient's skin, including said selected volume;

5 said second end of the waveguide having an aperture at least substantially as great as the aperture of radiation back-scattered from the patient's skin, the back-scattered radiation being substantially internally reflected within said waveguide; and

a reflector within said waveguide for returning back-scattered radiation through the waveguide to the patient's skin.

10

28. A system as claimed in claim 27 wherein said reflector is at said first end of the waveguide.

29. A system as claimed in claim 28 wherein said reflector is also along at least a portion of
15 waveguide sidewalls, and wherein said reflector has a coefficient of reflection at areas thereof such that backscattered radiation at angles nearer perpendicular to said skin contacting second end are reflected more strongly than back scattered radiation at angles nearer parallel to said second end.

20 30. A head for applying EM radiation of a wavelength appropriate for treating a selected patient dermatologic problem at a selected volume of a patient's skin, the head comprising:

an optical waveguide;

a light path for directing the EM radiation to a first end of the waveguide, said waveguide having a skin-contacting second end which is opposite said first end;

25 some of the radiation passing through the waveguide to a patient's skin being back-scattered over a back-scatter aperture, said second end of the waveguide being at least part of a reflection aperture at least substantially as great as said back-scatter aperture, back-scattered radiation entering the waveguide being substantially internally reflected within said waveguide; and

30 a reflector within said waveguide for returning the back-scattered radiation entering the waveguide through the waveguide to the patient's skin.

31. A head as claimed in claim 30 wherein said reflector is at said first end of the waveguide.

32. A head as claimed in claim 31 wherein said reflector is also along at least a portion of waveguide sidewalls, and wherein said reflector has a coefficient of reflection at areas thereof
5 such that backscattered radiation entering the waveguide at angles nearer perpendicular to said skin contacting second end are reflected more strongly than back scattered radiation entering at angles nearer parallel to said second end.

33. A head as claimed in claim 30 wherein said waveguide is cooled, and means for
10 maintaining a moisture-free environment for said reflector to inhibit condensation thereon.

34. A head as claimed in claim 30 wherein said second end of the waveguide has an aperture at least substantially as great as the aperture of radiation back-scattered from the patient's skin.

15 35. A head as claimed in claim 30 including a reflector plate surrounding said waveguide at the second end thereof, the combined area of the plate and the waveguide projecting therethrough being substantially equal to the aperture of radiation back-scatter.

36. A head as claimed in claim 35 wherein said plate has a concave shape.
20

37. A head as claimed in claim 35 including a means for controlling the temperature of the plate.

38. A head for applying EM radiation of a wavelength appropriate for treating a selected
25 patient dermatologic problem at a selected volume of a patient's skin, the head comprising:
a skin-contacting surface;

at least one light path passing through said head and terminating at said skin-contacting surface, said EM radiation being applied through said at least one light path to the patient's skin;

some of the radiation passing through the waveguide to a patient's skin being back-
30 scattered over a back-scatter aperture, said head including reflection means for returning back-scattered radiation to the patient's skin, said reflection means having a reflection aperture at least substantially as great as said back-scatter aperture.

39. A head as claimed in claim 38 wherein said reflection means includes at least a portion of said skin-contacting surface being formed as a reflection plate.

40. A head as claimed in claim 39 wherein some of the back-scattered radiation enters said light path, and wherein said reflection means includes at least one reflection surface for the back-scattered radiation entering the light path.

41. A head as claimed in claim 40 wherein at least a part of said at least one reflection surface is in said light path.

42. A head for applying EM radiation of a wavelength appropriate for treating a selected patient dermatologic problem at a selected volume of a patient's skin, the head comprising:
at least one optical waveguide for receiving said EM radiation and for directing it to a skin-contacting surface of the at least one waveguide;

a standoff having a first and second end, the first end surrounding said at least one waveguide at its lower end and forming a substantially air-tight seal therewith, and said second end being adapted to contact the patient's skin over said selected volume to form a chamber between said skin-contacting waveguide surface, the patient's skin and walls of the standoff;

and means for creating negative pressure in said chamber to draw the patient's skin therein and into contact with said skin-contacting surface.

43. A head as claimed in claim 42 wherein the walls of said standoff are reflective to return back-scattered radiation to the patient's skin.

44. A head as claimed in claim 42 wherein said means for creating negative pressure includes a hose mounted at one end to open into said chamber and connected at its other end to a source of negative pressure.

45. A head as claimed in claim 42 wherein said means for creating negative pressure includes the walls of said standoff being deformable when pressure is applied to the waveguide to permit the skin-contacting surface of the waveguide to contact the patient's skin, forcing most of the air

from said chamber, said walls returning to their undeformed state when pressure is released resulting in the creation of negative pressure in said chamber.

46. A head as claimed in claim 45 wherein said walls of the standoff are in the form of a bellows.

47. A head as claimed in claim 45 wherein said walls of the standoff are in the form of a suction cup.

48. A head as claimed in claim 45 wherein said walls of the standoff are in the form of an elastic ring.

49. A head for applying EM radiation of a wavelength appropriate for treating a selected patient dermatologic problem at a selected volume of a patient's skin, the head comprising:

at least one first optical waveguide for receiving said EM radiation and for directing it to an output surface of the at least one waveguide; and

a second optical waveguide having a first surface mounted to the output surface of the first optical waveguide to receive said EM radiation therefrom and having a second skin-contacting surface opposite said first surface, said skin-contacting surface having a larger area than said output surface and said second waveguide being formed to provide a larger optical aperture than that of said first waveguide.

50. A head as claimed in claim 49 wherein the ratio of the spacing between said first and second surfaces of the second waveguide and a selected surface dimension of said second surface is approximately 1.5 to 1.0.

51. A head as claimed in claim 50 wherein said selected surface dimension is one of the length of a side of said second surface and a diameter of said second surface.

52. A head as claimed in claim 49 including means for reflecting radiation back-scattered from the patient's skin into said second waveguide back into the patient's skin.

53. A head as claimed in claim 52 wherein said means for reflecting including forming at least a portion of said first surface so as to reflect radiation impinging thereon.

54. A head as claimed in claim 53 wherein said reflector is also along at least a portion of waveguide sidewalls, and wherein said reflector has a coefficient of reflection at areas thereof such that backscattered radiation entering the waveguide at angles nearer perpendicular to said skin contacting surface are reflected more strongly than back scattered radiation entering at angles nearer parallel to said skin contacting surface.

55. A head for applying EM radiation of a wavelength appropriate for treating a selected patient dermatologic problem at a selected volume of a patient's skin, the head comprising:

a skin-contacting surface;

at least one light path passing through said head and terminating at said skin-contacting surface, said EM radiation being applied through said at least one light path to the patient's skin;

and

a temperature sensor located in said head within a few millimeters of said skin contacting surface.

56. A head as claimed in claim 55 wherein said temperature sensor is located within 5 mm of said skin contacting surface.

57. A head as claimed in claim 55 wherein said head is moved across a patient's skin during treatment, and including a head portion of a thermally conductive material passing over the skin prior to said at least one light path, a said temperature sensor being located in said head portion.

58. A head as claimed in claim 57 including means for one of heating and cooling said head portion to preheat/precool the patient skin prior to application of EM radiation thereto.

59. A head as claimed in claim 57 including means for heating said head portion to preheat the patient's skin prior to application of EM radiation thereto, and means for utilizing the output of said temperature sensor in response to the preheating to determine patient skin type.

1/10

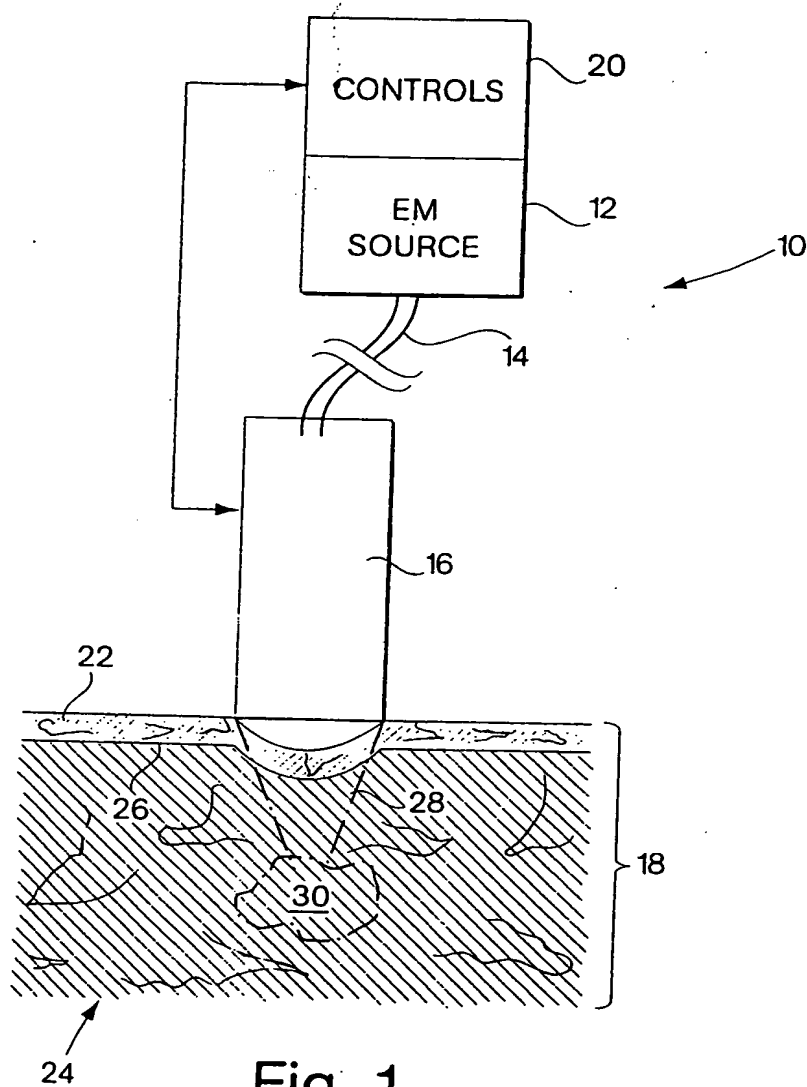


Fig. 1

This Page Blank (uspto)

2/10

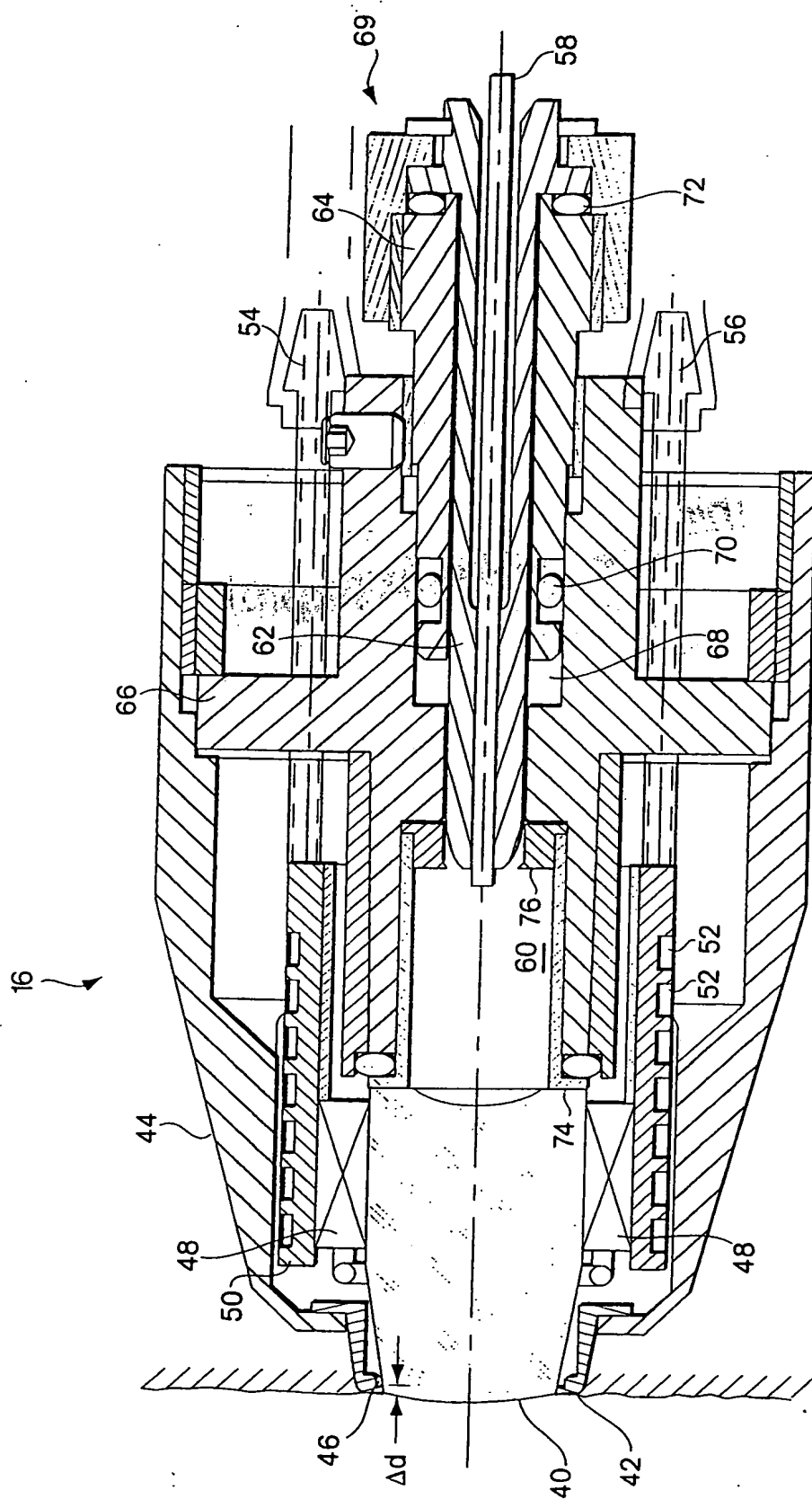


Fig. 2

This Page Blank (uspto)

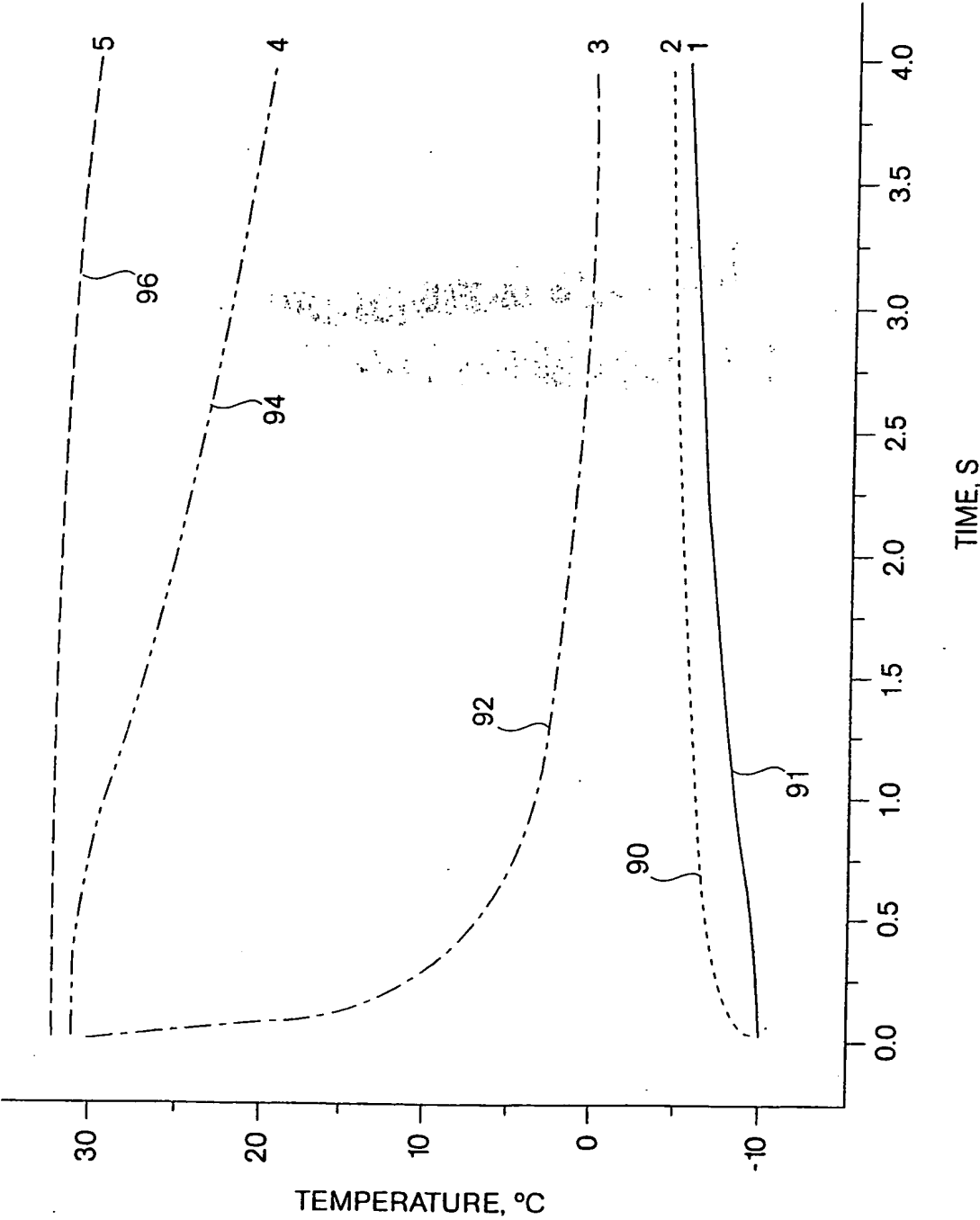


Fig. 3a

This Page Blank (uspt

4/10

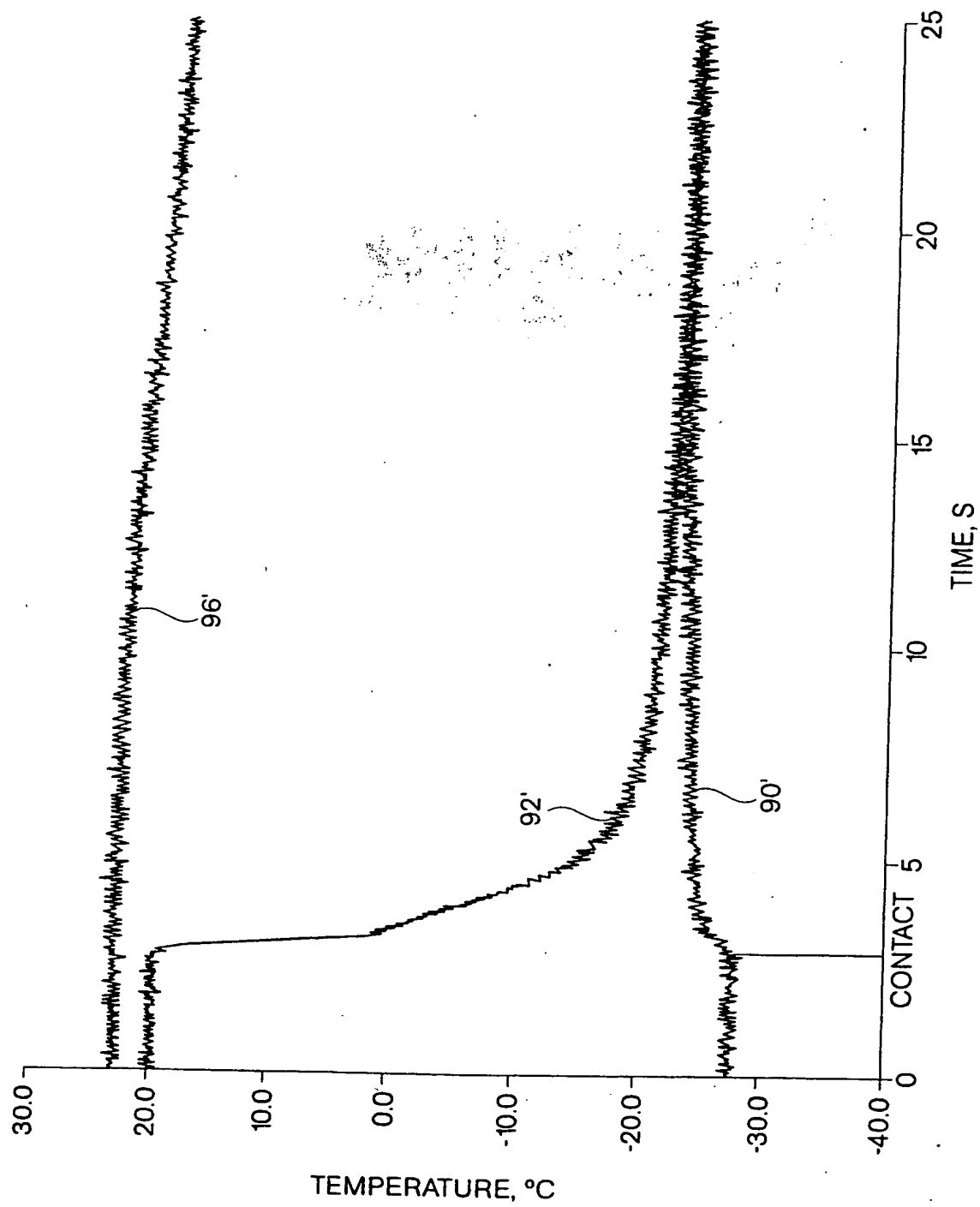


Fig. 3b

This Page Blank (uspto)

5/10

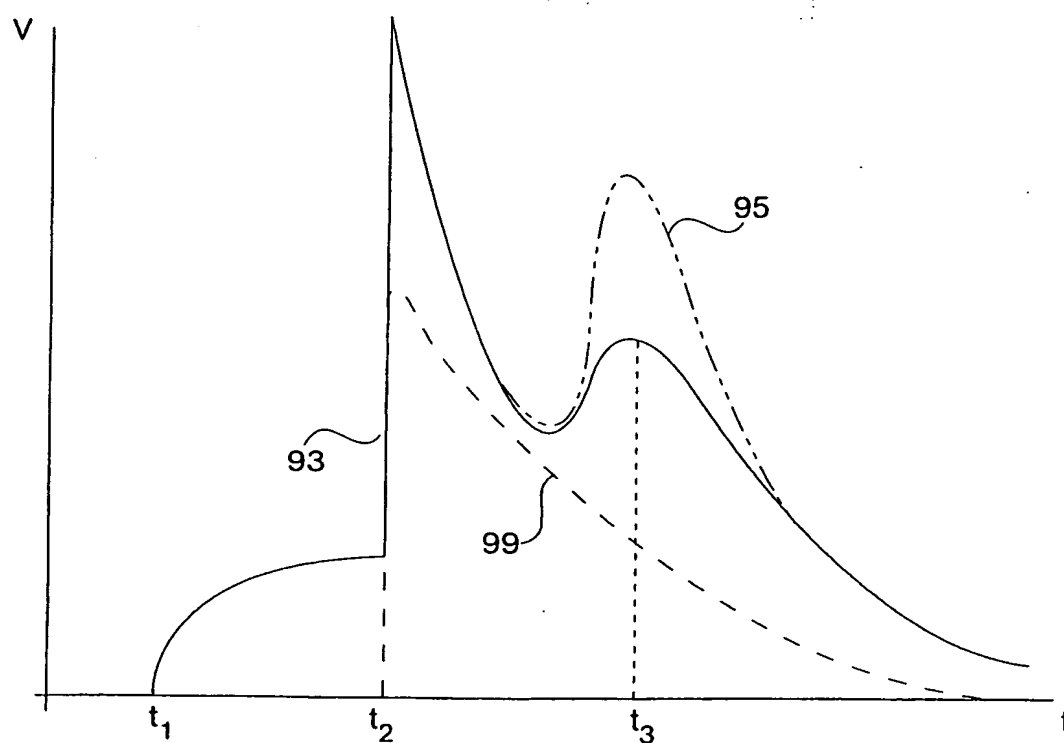


Fig. 4

This Page Blank (uspto)

6/10

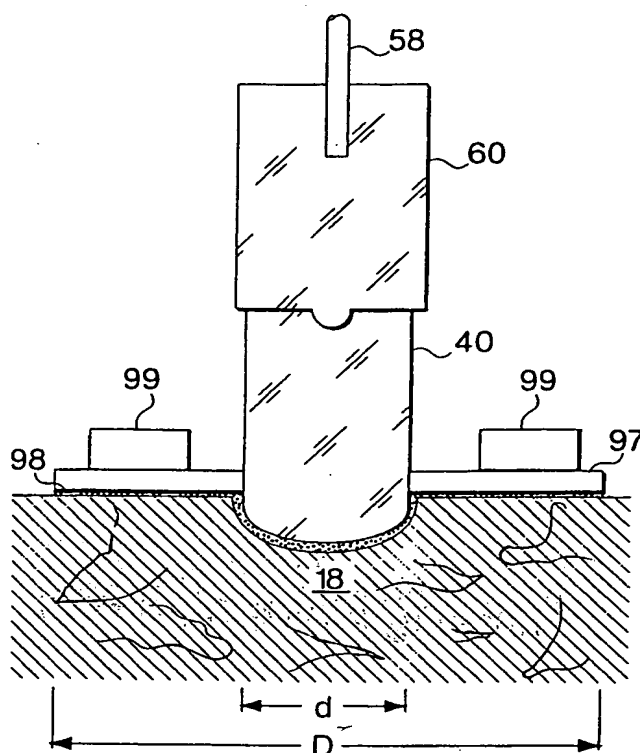


Fig. 5a

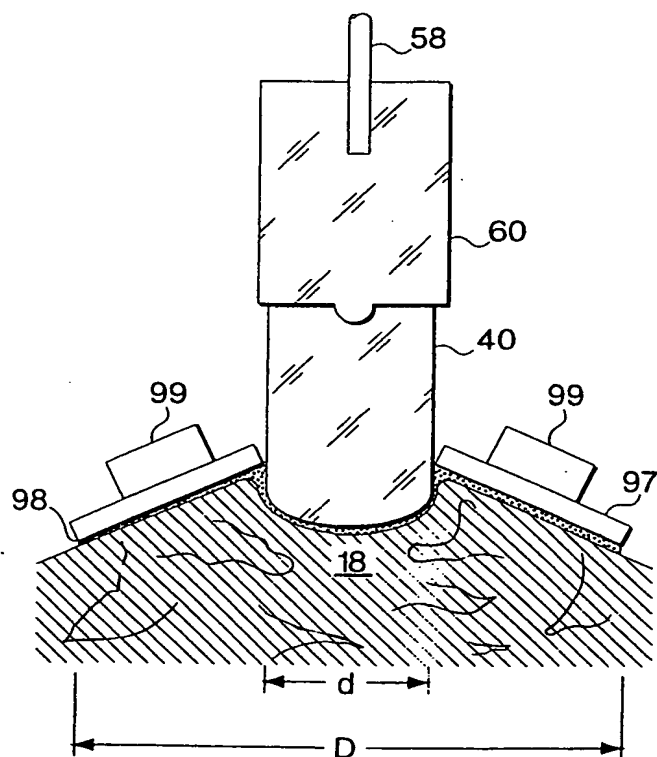


Fig. 5b

This Page Blank (uspto

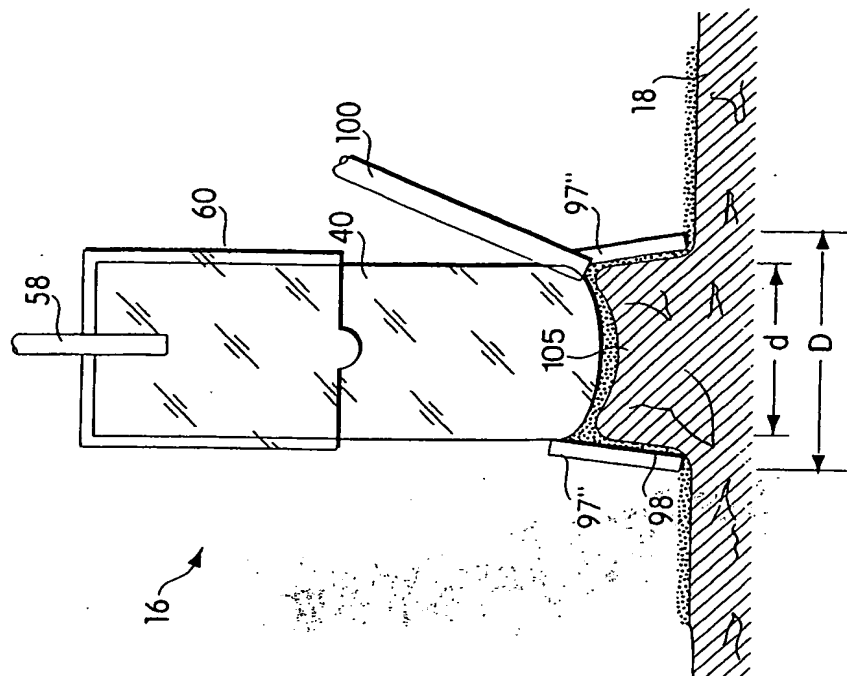


Fig. 6a

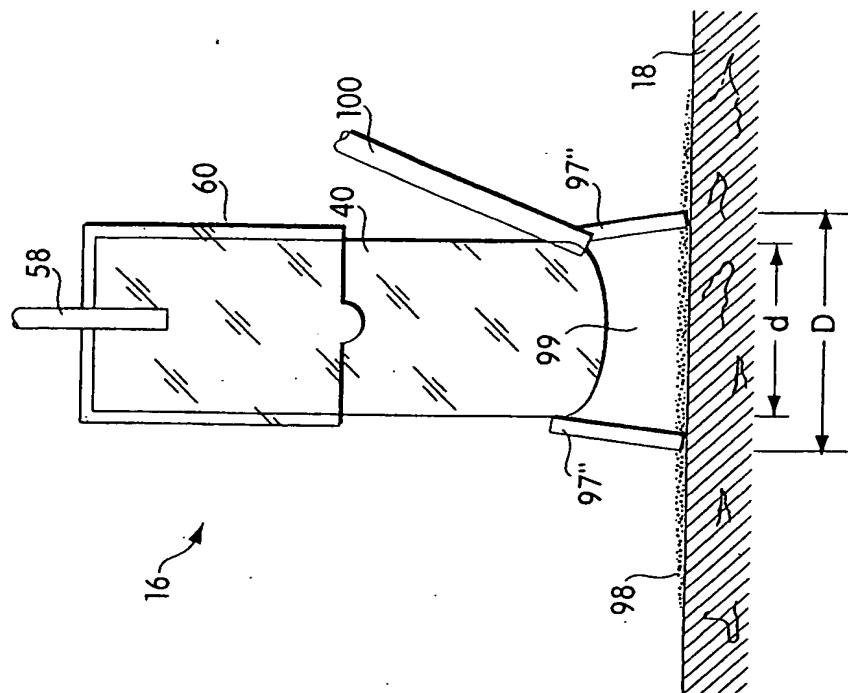


Fig. 6b

This Page Blank (uspt

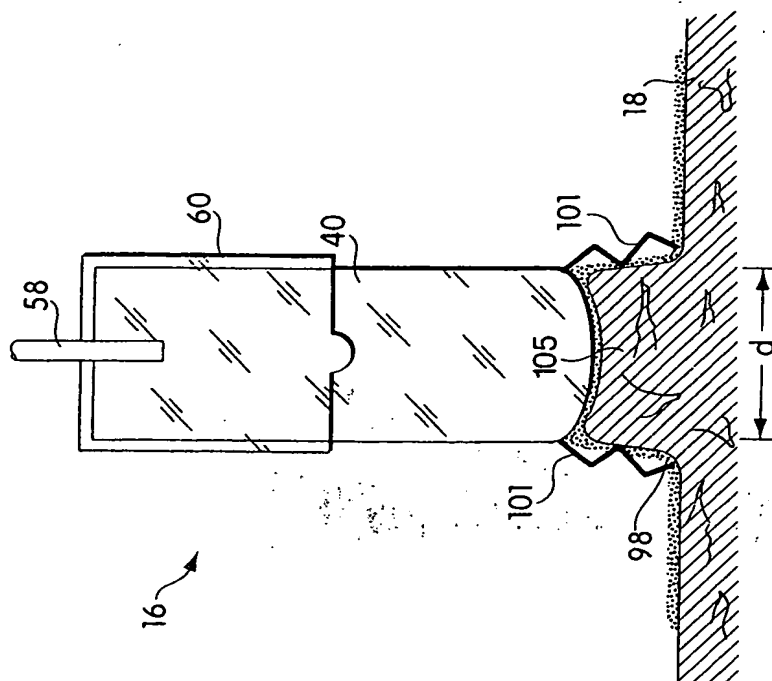


Fig. 7b

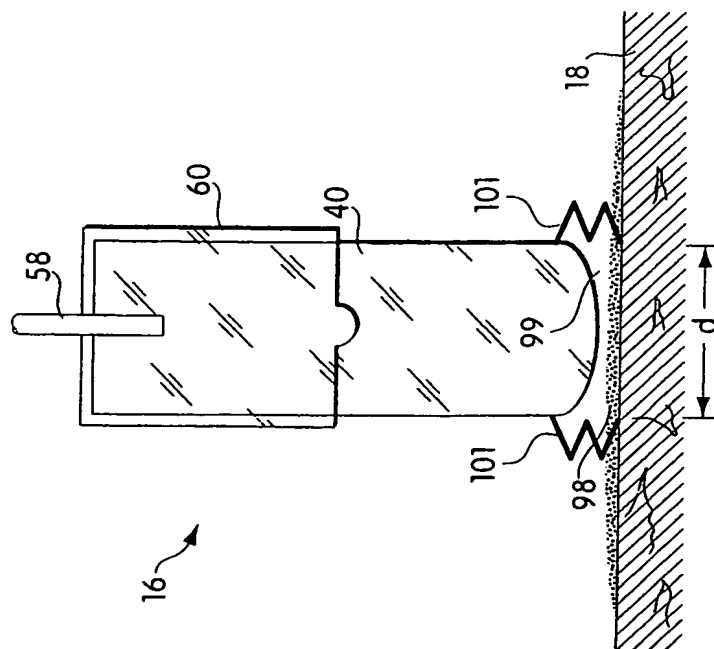


Fig. 7a

This Page Blank (uspto)

9/10

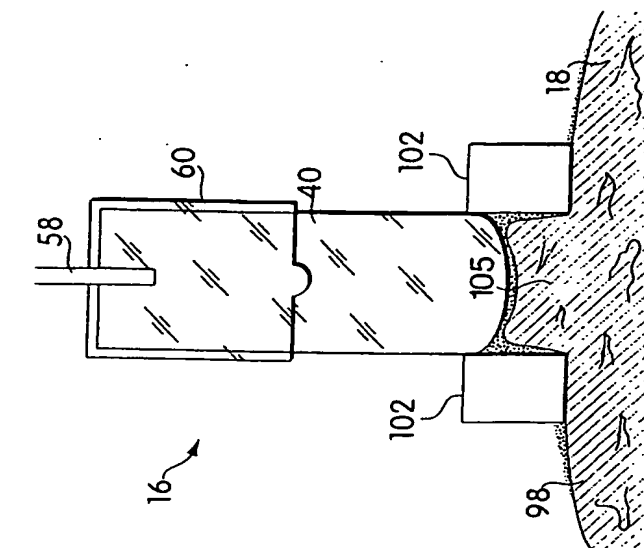


Fig. 8a

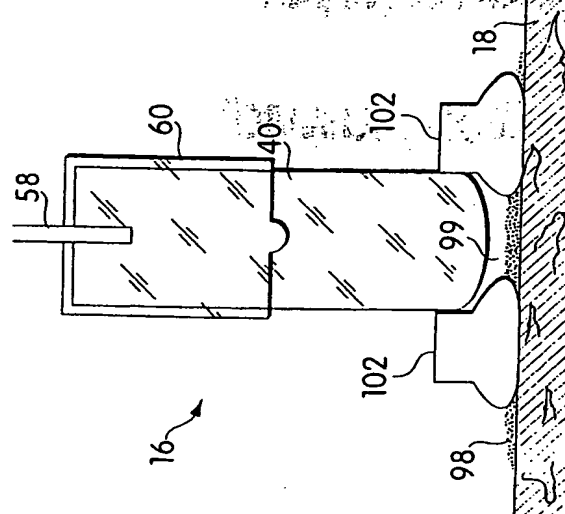


Fig. 8b

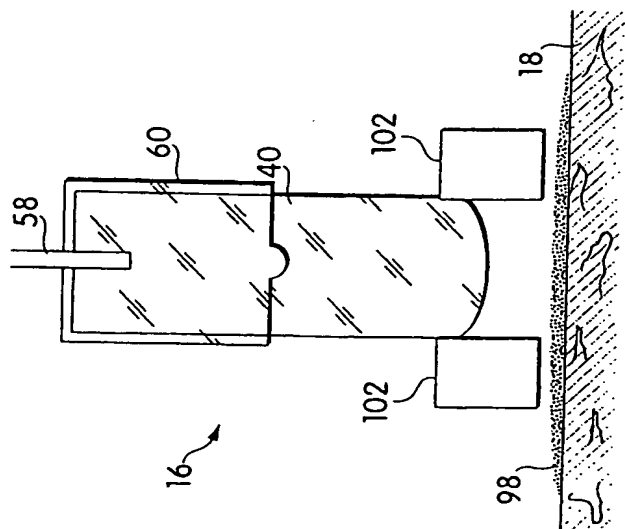


Fig. 8c

This Page Blank (uspto)

10/10

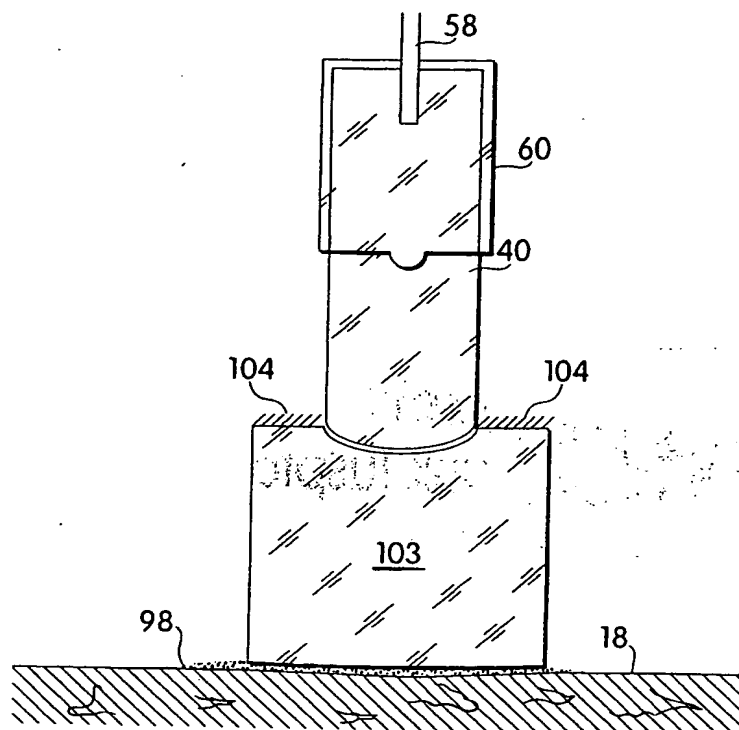


Fig. 9

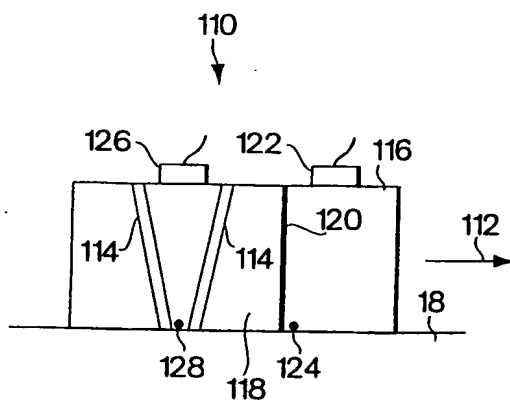


Fig. 10

This Page Blank (uspto)

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/05501

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 783 904 A (ESC MEDICAL SYSTEMS LTD) 16 July 1997 see column 1, line 34 - line 40 see column 5, line 50 - column 6, line 10; figure 2 see column 6, line 32 - line 39 see column 7, line 15 - line 41	1-7, 16-18, 20, 21, 55-58
Y	---	8, 9, 13, 14
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

2 July 1999

Date of mailing of the international search report

09/07/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Petter, E

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/05501

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 90 00420 A (ALLARDICE JAMES TODD ; ROWLAND ADRIAN CHARLES (GB)) 25 January 1990 see page 12, line 1 - page 14, line 18; figures 1-5	38-41
Y		8,9,13, 14
A		27-37, 49,53
X	WO 97 13458 A (GEN HOSPITAL CORP) 17 April 1997 see page 7, line 22 - page 9, line 7	38-41
A		8,9,13, 14, 27-37, 49,53
X	AT 400 305 B (DIVIDA GMBH) 27 December 1995 see page 3, line 48 - page 4, line 2; claim 1	42,44,47
A	FR 2 591 902 A (COLLIN YVON) 26 June 1987 see page 5, line 10 - page 6, line 12	42-45,47
A	WO 95 32441 A (US HEALTH) 30 November 1995 see page 7, line 7 - page 10, line 10; figures 1A,1B	49-54
A	WO 98 04317 A (LIGHT SCIENCES LIMITED PARTNER) 5 February 1998 see page 7, line 29 - line 35	58,59

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/05501

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

SEE ADDITIONAL SHEET

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1,8-15,27-41 Improving a light conductor in such a way that back-scattered radiation from the skin is reflected.
2. Claims: 16-26 Triggering onset of radiation by measuring the thermal profile.
3. Claims: 42-48 Improving physical contact with the skin by suction.
4. Claims: 49-54 A second optical waveguide applied to the first waveguide.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/05501

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0783904	A	16-07-1997	US 5849029 A		15-12-1998
			AU 7641996 A		03-07-1997
			CA 2193193 A		27-06-1997
			JP 9187522 A		22-07-1997
WO 9000420	A	25-01-1990	AU 3977389 A		05-02-1990
WO 9713458	A	17-04-1997	US 5824023 A		20-10-1998
			AU 7662196 A		30-04-1997
			CA 2234455 A		17-04-1997
AT 400305	B	27-12-1995	AT 46794 A		15-04-1995
FR 2591902	A	26-06-1987	NONE		
WO 9532441	A	30-11-1995	US 5519534 A		21-05-1996
			AU 2651795 A		18-12-1995
WO 9804317	A	05-02-1998	US 5814008 A		29-09-1998
			AU 3503997 A		20-02-1998

This Page Blank (uspto)